REMARKS

I. Support for the Amendments

Non-elected claims 6, 7, and 11-13 have been canceled without prejudice to or disclaimer of the underlying subject matter. Claims 1-3 and 8 have been amended to recite the elected SEQ ID NO and claim 5 has been amended to correct typographical errors. Claims 14-18 have been added. Support for the foregoing claim amendments may be found throughout the specification, in the sequence listing, and in the original claims, for example, from page 2, line 15 through page 3, line 15, and from page 12, line 14 through page 13, line 27. Upon entry of the foregoing amendments, claims 1-5, 8-10, and 14-18 are pending in the application. No new matter enters by way of these amendments.

II. The Restriction Requirement

Applicants acknowledge the finality of the restriction requirement to claims 1-5 and 8-10 but maintain their traversal. To facilitate prosecution, however, Applicants have removed the non-elected claims from the application.

Applicants also acknowledge the finality of the election requirement to a single group of nucleotide sequences, but maintain their traversal. However, in order to facilitate prosecution, Applicants have removed non-elected sequences from the claims.

III. Information Disclosure Statement

Applicants acknowledge and thank the Examiner for including an initialed copy of the Information Disclosure Statement (Form PTO-1449), filed on December 20, 2001, with this Office Action.

IV. Sequence Listing

Applicants thank the Examiner for indicating that the computer-readable and paper sequence listings have been entered.

V. Objection to the Specification

The specification has been objected to for purportedly containing embedded hyperlink and/or other form of browser-executable code. Office Action at page 3. Applicants respectfully disagree.

The purpose of the requirement that hyperlinks or other forms of browser executable code be removed from the specification is so that, on the United States Patent and Trademark Office web site, one cannot click on the hyperlink and be transported to another, potentially commercial, web site. This requirement does not exclude the listing of a web site that is not present as a hyperlink.

Although it may be possible to click on this purported "hyperlink" in a Microsoft Word document and be transported to the corresponding web site, or even to copy and paste this purported "hyperlink" into the address location in Microsoft Explorer, this purported "hyperlink" would not be usable when placed on the United States Patent and Trademark Office web site. For example, a search of the United States Patent and Trademark Office patent database using "www.ncbi.nlm.nih.gov" as search term identified 71 patents citing this web site, including U.S. Patent No. 6,552,250 (patent database last accessed on October 10, 2003). In the '250 patent, the citation of this web site using a format similar to that used by Applicants does not result in a useable hyperlink. Therefore, the citation of a web site in this format does not offend United States Patent and Trademark Office policy, and should be allowed in an application. Moreover, the purported hyperlinks in the present specification do not contain browser-executable code in the absence of embedded hyperlinks and/or other forms of browser-executable code (see, e.g., page 10 of the Application). *See* MPEP § 608.01.

In light of these remarks, Applicants respectfully request withdrawal of this objection to the specification.

VI. Rejection of Claims 1-5 and 8-10 under 35 U.S.C. § 101, Utility

The Examiner has rejected claims 1-5 and 8-10 under 35 U.S.C. § 101, for allegedly lacking a patentable utility. Office Action at pages 3-5. Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification discloses that the claimed invention can be used "to develop nutritionally and agriculturally enhanced crops and products" and "aid gene expression studies that allow the dissection and elucidation of commercially useful traits." Office Action at pages 3-4. However, the Examiner contends that the present invention lacks "a specific, substantial asserted utility or a well established utility." Office Action at page 3. Applicants respectfully disagree.

It is well established that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 298 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention. The claimed nucleic acid molecules are useful for isolating a variety of agronomically significant genes, acquiring molecular markers, promoters, and transcriptional regulatory elements, identifying polymorphisms, etc. *See, e.g.*, the section under the heading "Exemplary Uses" in the specification starting at page 38.

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell or organism. Significantly, the utility of the microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize other nucleic acid molecules within a sample, cell or organism. Such utility

is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed nucleic acid molecules possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather, the Examiner attempts to undermine the existing utilities by stating that "this asserted utility is not specific to any particular class or group of plant genes, as most if not all plant genes would fulfill this asserted utility." *Id.* In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law–there is no requirement of exclusive utility in patent law. *See Carl Zeiss Stifung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result . . . .").

Such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.,* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 306 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.,* 289 U.S. 178, 199, 17 U.S.P.Q. 154, 163 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

As noted above, the claimed nucleic acid molecules have many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and locate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically

hitting a golf ball, but is uniquely designed to hit a ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

The Examiner also states that the credibility of the presently asserted utilities has not been established and cannot be assessed. Office Action at page 5. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 752 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the United States Patent and Trademark Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question–[he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided . . . ."). Here the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1-2 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 3-5 and 8-10 are drawn to host cells and plants transformed with the nucleic acids in claims 1-2 and stand rejected on the same alleged grounds. For at least the foregoing reasons, Applicants respectfully traverse this rejection. Additionally, one of the specific and substantial utilities of such transformed cells and plants is to yield the nucleic acids in claims 1-2 to realize the latter's utility. Therefore, reconsideration and withdrawal of this rejection are respectfully requested.

VII. Rejection of Claims 1-5 and 8-10 under 35 U.S.C. § 112, First Paragraph, Enablement

The Examiner has rejected claims 1-5 and 8-10 as allegedly not being enabled by the specification, because the claimed invention allegedly lacks utility. Office Action at page 5. Applicants respectfully disagree and assert that the rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Reconsideration and withdrawal of the rejection are respectfully requested.

The Examiner has also rejected the recitation of "fragments thereof" in claim 8 as allegedly not enabled. Applicants respectfully disagree, as claim 8 is clear when read in light of the specification. *See, e.g.*, specification at page 10, lines 1 through 22. However, in order to facilitate prosecution, Applicants have amended claim 8 with respect to the phrase "fragment thereof" and submit that the indefiniteness rejection should be withdrawn as inapplicable to the presently amended claims.

VIII. Rejection of Claims 1-5 and 8-10 under 35 U.S.C. § 112, Second Paragraph, Definiteness

The Examiner has rejected claims 1-5 and 8-10 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Office Action at page 6. Applicants respectfully disagree.

Claims 1 and 2 stand rejected as allegedly indefinite. The Examiner asserts that the definition for "substantially purified" given in the specification is circular in that Applicants defines "substantially purified" as a molecule separated from substantially all other molecules normally associated with it. Applicants respectfully disagree. A definition given in the specification should not be read in a truncated form and taken out of its context. Applicants submit that when read in its entirety, as provided in page 8, lines 20-26 of the specification, "substantially purified" is defined in a manner free of circularity or indefiniteness. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1 and 3 stand rejected as allegedly indefinite "as 'complements' may read on a single base." Office Action at page 6. Applicants respectfully disagree. It is submitted that the recitation of "complement" in the amended claims is definite when read in light of the specification. *See* specification at page 11, lines 4-7. However, in order to facilitate prosecution, Applicants have amended the claims. Therefore, reconsideration and withdrawal of the rejection are respectfully requested.

Claim 8 stands rejected as allegedly indefinite in the recitation of "structural nucleic acid." Office Action at page 6. Applicants respectfully disagree. Applicants respectfully point out that the claims are to be read in light of the specification. *See In re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970). The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), *cert. denied*, 112 S. Ct. 169 (1991). Furthermore, "[t]he mere fact that a term or phrase used in the claims has no antecedent basis in the specification disclosure does not mean, necessarily, that the term or phrase is indefinite. There is no requirement that the words in the claim must match those used in the specification disclosure." MPEP § 2173.05(e).

Applicants respectfully assert that the meaning of the phrase "structural nucleic acid" is readily understandable by one of skill in the art, particularly when considered in the context of the other phrases of claim 8. Moreover, one skilled in the art would readily

recognize the distinction between a structural nucleic acid molecule and a non-structural nucleic acid molecule. Applicants therefore respectfully request reconsideration and withdrawal of the indefiniteness rejection of claim 8 under 35 U.S.C. § 112, second paragraph.

IX. Rejection of Claims 8-10 under 35 U.S.C. § 102

Claims 8-10 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 4,956,282 granted to Goodman *et al.* Goodman teaches "transformed maize and soybean expressing interferon, wherein said plant contains a plant functional promoter, structural gene and non-translated terminated sequence (col. 4, ln 59, col. 2, ln. 28-33)." Office Action at page 7. The Examiner's position is based on the allegation that "[t]he 'comprising' and 'fragments thereof' without any recited function language read on a transformed plant expressing any protein of interest (emphasis added by Applicants)." Office Action at page 7. Applicants respectfully disagree.

"It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q 619 (Fed. Cir. 1985).

In the present application, pending claim 8, as amended, together with dependent claims thereof, is directed to a transformed plant having a nucleic acid molecule which comprises a structural nucleic acid molecule encoding a protein comprising an amino acid sequence of SEQ ID NO: 45. Whatever Goodman teaches, it does not disclose SEQ ID NO: 45. Absent a teaching of each and every element of the claim, including the amino acid sequence of SEQ ID NO: 45, the reference cited by the Examiner does not anticipate claim 8 and dependent claims thereof.

In view of the above, Applicants contend the rejection under 35 U.S.C. § 102(b) is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

In view of the above, the presently pending claims are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned with respect to any unresolved issues remaining in this application.

Respectfully submitted,

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